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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,160

03/25/2004

Myeong-Je Cho

416272001301

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09/08/2006

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/810,160	Applicant(s) CHO ET AL.	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-34,36-38,40-43,77,79-81,83-86 and 112-125 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 32-34,36-38,40-43,77,79-81,83-86 and 112-125 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/6/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

Sequence Rules

1. The drawings are objected to. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825. Specifically, Figures 6 and 7. Applicant must submit a CRF copy and paper copy of the Sequence Listing, a statement that the content of the paper and computer readable copies are the same and where applicable include no new matter as required by 37 C.F.R. § 1.821(e) or 1.821(f) or 1.821(g) or 1.825(d), as well as an amendment directing its entry into the specification. If the disclosed sequences are in the Sequence Listing of record, then an amendment to the specification, Brief Description of the Figures, would correct this objection.

Failure to comply with these requirements in response to this Office Action will be considered non-responsive to this Office Action.

Specification

2. The abstract of the disclosure is objected to because it is not specifically directed to the claimed invention. Correction is required. See MPEP § 608.01(b).
3. At page 58, line 22, the incorporation by reference of USP App. 08/21,673 should be amended to reference the issued US Patent 6,113,951.

Information Disclosure Statement

4. The listing of references in the specification, pages 62-68, is not a proper information disclosure statement. 37 CFR § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
5. The IDS filed 6 May 2004 has been considered, a signed copy is attached hereto.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Claims 32-34, 36-38, 40-43, 77, 79-81, 83-86 and 112-125 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,784,346. Although the conflicting claims are not identical, they are not patentably distinct from each other because The transgenic monocot plant selected from barley and wheat of issued claim 1 of the '346 patent renders obvious the broader invention of instant claim 32 directed to any transgenic monocot plant comprising a recombinant nucleic acid encoding a thioredoxin h polypeptide operably linked to a seed or grain maturation-specific promoter.

Claim Rejections - 35 USC § 112

8. Claims 32-34, 36-38, 40-43, 77, 79-81, 83-86, 112-125 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a transgenic monocot plant comprising a recombinant nucleic acid comprising a seed or grain maturation-specific promoter operably linked to a nucleic acid molecule encoding the thioredoxin h of SEQ ID NO: 25 or the wheat thioredoxin h of the prior art, does not reasonably provide enablement for a transgenic monocot plant comprising a recombinant nucleic acid comprising a seed or grain maturation-specific promoter operably linked to a nucleic acid molecule encoding any thioredoxin h. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants claim a transgenic monocot plant wherein at least part of said plant comprises a recombinant nucleic acid comprising a promoter active in said part

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operably linked to a nucleic acid molecule encoding a thioredoxin h polypeptide wherein said promoter is a seed or grain maturation-specific promoter, and in a broader sense any transgenic seed or grain comprising a recombinant nucleic acid comprising a promoter active in said seed or grain operably linked to a nucleic acid molecule encoding thioredoxin h polypeptide wherein said promoter is a seed or grain maturation-specific promoter.

Applicant teaches transgenic wheat and sorghum transformed with the barley thioredoxin h of SEQ ID NO: 25 or the thioredoxin h from wheat of the prior art, operably linked to a hordein promoter.

Applicant does not teach other transgenic plants transformed with other thioredoxin h encoding nucleic acids operably linked to a seed or grain maturation-specific promoter.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance on how to make and use transgenic plants comprising a recombinant nucleic acid encoding a thioredoxin h polypeptide. The art teaches that thioredoxin h polypeptides regulate a wide variety of physiological

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functions in a plant. Laloi *et al* (2004, Plant Physiology 134:1006-1016) teach that the Arabidopsis cytosolic thioredoxin h5 gene product has a role not shared with other thioredoxin h polypeptide known from Arabidopsis (see the abstract on page 1006). Gelhaye *et al* (2004, Proceedings of the National Academy of Science, USA 101(40): 14545-14550) teach a plant thioredoxin h gene products associated with plant mitochondria, the PtTrxh2. Galhaye *et al* also teach that there are three different subgroups of plant thioredoxin h polypeptides, and that those from cereals define a distinct cluster (Figure 2 on page 14547). Applicant only teaches how to make and use transgenic plants by expressing the barley thioredoxin h of SEQ ID NO: 25 or the thioredoxin h from wheat of the prior art, encoding recombinant nucleic acid operably linked to a hordein promoter to increase starch metabolism and germination in germinating, transgenic monocot seeds. Applicant provides no guidance on how to make and use transgenic plants using any thioredoxin h encoding recombinant nucleic acid that has no effect on starch metabolism or germination. It would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use a myriad of monocot or other plants (instant claim 77) transformed with a recombinant nucleic acid encoding any thioredoxin h polypeptide as broadly claimed. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC § 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in

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the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.”.

9. Claims 40, 83, 114 and 115 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a transgenic plant comprising a recombinant nucleic acid encoding a barley thioredoxin h polypeptide.

Applicants describe a single species of barley thioredoxin h polypeptide in SEQ ID NO: 25, and thus recombinant nucleic acids encoding said polypeptide.

Applicants do not describe nucleic acids encoding a genus of barley thioredoxin h polypeptide.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without

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any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Gelhaye *et al* (2004, Proceeding of the National Academy of Science, USA 101(40): 14545-14550) teach that plants have many genes encoding thioredoxin polypeptides at page 14545, left column. Hence, Applicant does not appear to adequately describe the genus of thioredoxin h polypeptide encoding nucleic acids as broadly claimed.

10. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "131 hordein" does not appear to be an art recognized term, and the specification does not define this term, hence the metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 32-34, 36-38, 40-43, 77, 79-81, 83-86, 112, 113 and 116-125 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lappegard *et al* (U.S. Patent 6,225,529 B1, issued 1 May 2001 and claims priority to U.S. Provisional Application

60/097,233, filed 20 August 1998) in view of Gautier *et al* (1998, Eur. J. Biochem. 252: 314-324) and Besse *et al* (1996, Proc. Natl. Acad. Sci. USA 93: 3169-3175) and in further view of Sorensen *et al* (1996, Mol. Gen. Genet. 250: 750-760).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Lappegard *et al* teach a transgenic monocot plant and seed comprising a maize zein promoter, which is capable of initiating seed-preferred transcription of a recombinant nucleic acid, operably linked to a nucleic acid sequence at claims 23-26. Lappegard *et al* teach that the promoter of the invention can be used for varying the phenotype of seeds such as altering the starch or carbohydrate profile (column 5, 2nd paragraph).

Lappegard *et al* do not teach using a recombinant nucleic acid encoding a thioredoxin h polypeptide to make a transgenic plant or seed. Lappegard *et al* do not teach using a hordein D promoter.

Gautier *et al* teach a recombinant nucleic acid encoding two wheat thioredoxin h polypeptides at Figure 2, page 318. Gautier *et al* also teach other a recombinant nucleic acid encoding other thioredoxin h polypeptides from *Nicotiana tabacum*, *Oryza sativa*, *Brassica napus* and *Arabidopsis thaliana*, for example, at Figure 2. Gautier *et al*

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teach that the wheat thioredoxin h polypeptides naturally comprise a signal or transit peptide at page 321, left column, 3rd paragraph.

Besse *et al* teach that thioredoxin was a well-known cellular agent involved modifying the contents of germinating wheat seeds (page 3173, right column, 4th paragraph). Besse *et al* teach that one of ordinary skill in the art at the time of Applicant's invention would understand that thioredoxin has a role in germination by enhancing proteolysis through the activation of thiolcalsin and reducing storage proteins and neutralizing enzyme inhibitor proteins (page 3174, right column, 2nd paragraph).

Sorensen *et al* teach the hordein D promoter, as acknowledged by Applicant on page 11, 4th paragraph, of the specification. Sorensen *et al* also teach that the hordein D promoter has the advantage of producing higher expression/activity and is unmethylated in endosperm, methylation being a means of inhibiting activity of a promoter region (Abstract on page 750).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Lappegard *et al* by using the wheat thioredoxin encoding nucleic acids taught by Gautier *et al*. It would have also been obvious to substitute the zein promoter of Lappegard *et al* with the hordein D promoter of Sorensen because the hordein D promoter gives high expression in the endosperm of a seed. The teachings of Besse *et al* teach that in wheat thioredoxin is a critical feature of seed germination, a function also recognized by Gautier *et al* (see the abstract on page 314). Lappegard *et al* had taught that the seed-specific zein promoter could be used to modify the carbohydrate content of seed, a feature of thioredoxin h

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that was known in the art at the time of Applicants' invention. Applicants state that germination in transgenic barley overexpressing wheat thioredoxin h was detected about 16 hours after the onset of incubation and that non-transgenic seed showed no germination (paragraph spanning pages 40-41 of the specification). This evidence does not appear to lead to a teaching of unexpected results, given that the prior art recognized that thioredoxin h was involved in seed germination in wheat.

Conclusion

14. Claims 40, 83, 114 and 115 are free of the prior art because it fails to teach or suggest a recombinant nucleic acid encoding a barley thioredoxin h polypeptide.

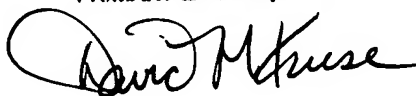
15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

**DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER**



David H. Kruse, Ph.D.
1 September 2006

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17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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